REMARKS

The present application has been reviewed in light of the non-final Office Action dated May 11, 2009. The May 11, 2009 Office Action indicates that prosecution in the present application has been reopened in view of the Appeal Brief filed on November 3, 2008. Accordingly, claims 1 and 5-11 are pending in the present application with claim 1 being in independent form. Claims 2-4 and 12-22 were previously cancelled.

Rejection of Claims – 35 U.S.C. §103(a)

In the May 11, 2009 Office Action, the Examiner rejected claim 1 under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 5,630,837 to Crowley (hereinafter "Crowley") in view of either obvious design considerations for a person skilled in the art or U.S. Patent No. 6,245,020 to Moore et al. (hereinafter "Moore").

On pages 2 and 3 of the May 11, 2009 Office Action, the Examiner alleged that Crowley discloses the subject matter of claim 1 except for the limitation of having "about 32 and 64 ultrasound transducers" on an ultrasound array. However, the Examiner alleged that Moore discloses an array having 32 circumferentially arranged transducer elements. Further, the Examiner alleged that the particular number of transducers being used is deemed to be an obvious design consideration for a person skilled in the art.

For at least the following reasons, Applicant respectfully submits that the subject matter of independent claim 1 is not rendered obvious by the combined teaching of Crowley in view of the teaching of Moore and/or obvious design considerations.

The present application describes an apparatus for ablating tissue. For example, the present application describes an apparatus having a catheter and an ultrasound device that is fed through the catheter to a targeted tissue. The ultrasound device is described as having an

ultrasound array comprising a plurality of ultrasound transducers arranged circumferentially around a device lead. Each ultrasound transducer is coupled via a wire to a control bus, which drives each of the ultrasound transducers such that the ultrasound array may function as a phased array. By driving the ultrasound array as a phased array, the ultrasound energy projected in any azimuthal direction can be controlled such that certain tissues can be targeted for treatment, while other tissues can be left untreated, allowing the healthcare professional to only treat desired regions of tissues while avoiding substantial energy application to surrounding tissue. The present application also describes imaging functionalities provided on the ultrasound device for imaging tissue near the ultrasound device thereby allowing the healthcare professional to assess the location and orientation of the ultrasound device and/or to analyze the surrounding tissue in order to locate particular targets for ablation.

Claim 1 is directed to an apparatus for use with a subject, comprising: (i) a catheter having a longitudinal axis and having distal portion, and (ii) an ultrasound array comprising between about 32 and 64 ultrasound transducers circumferentially arranged around the longitudinal axis at the distal portion, and adapted to operate in a phased array mode to apply ablating energy to tissue of the subject located in a range of azimuths, with respect to the longitudinal axis, that is less than 360 degrees, including a range of azimuths between 180 and 359 degrees, wherein when the catheter is threaded through the venous system and disposed in a vicinity of an ostium of a pulmonary vein of the subject, the range of azimuths is sufficiently smaller than 360 degrees to avoid inducing a deficit in a phrenic nerve of the subject.

Crowley, as presently understood by Applicant, describes a catheter system 500 including an array 502 of annular acoustic elements 504-514 for tissue ablation. Crowley further describes each annular acoustic element as including a transducer ring 526. Crowley states that

the annular configuration of the transducer ring 526 allows the physician to create 360° (i.e., ring-shaped) lesions without rotation of the catheter. See Crowley, column 3, line 48 through column 4, line 14.

Accordingly, Applicant respectfully submits that Crowley describes an array of annular transducers but does not teach or suggest the structural feature of an ultrasound array comprising ultrasound transducers circumferentially arranged around the longitudinal axis of the catheter and at the distal portion of the catheter, and adapted to operated in a phased array mode to apply ablating energy to tissue of a subject located in a range of azimuths, with respect to the longitudinal axis of the catheter, as set forth in claim 1.

On page 3 of the May 11, 2009 Office Action, the Examiner cited column 19, lines 4-14 of Moore as alleged disclosing a circumferentially arranged array of transducers.

Moore, as presently understood by Applicant, describes a catheter 230 for ultrasonic imaging of a vessel wall. The catheter 230 includes a catheter body 232 and a plurality of transducer elements 234 embedded in the distal end of the catheter body 232 and circumferentially arranged therearound to form a phased array.

Applicant respectfully submits that Moore describes, at best, transducer elements circumferentially arranged to form an ultrasonic array for imaging a vessel wall but does not teach or suggest an ultrasound array comprising ultrasound transducers circumferentially arranged around the longitudinal axis of the catheter and at the distal portion of the catheter, and adapted to operate in a phased array mode to apply ablating energy to tissue of a subject located in a range of azimuths, with respect to the longitudinal axis of the catheter, as set forth in claim 1.

On page 3 of the May 11, 2009 Office Action, the Examiner alleged that the claimed number of transducers (i.e., "between about 32 and 64 ultrasound transducers") is an obvious design consideration for a person skilled in the art.

Applicant respectfully submits that the Examiner has failed to recognize the criticality of the claimed number of transducers (i.e, between about 32 and 64 transducers) and the claimed range of azimuths for the applying ablating energy (i.e., between 180 and 359 degrees, and sufficiently smaller than 360 degrees to avoid inducing a deficit in a phrenic nerve of the subject) as clearly indicated in Applicant's specification at, for example, page 16, lines 21 to page 17, line 33.

Such features clearly enable Applicant's claimed apparatus to achieve remarkable unexpected results presently not found or even suggested in the cited prior art references. For example, see the ultrasound ablation energy profile for Applicant's phased array clearly indicated in Fig. 3B of the original disclosure which permits appropriate ablation energy to be applied to the vessel wall of the pulmonary vein and relatively less ablation energy to be applied to those tissue regions close to the phrenic nerve (a vital nerve in the pulmonary vein that must be avoided).

Furthermore, where a feature is not shown or suggested in the prior art references themselves, the Federal Circuit has held that the skill in the art will rarely suffice to show the missing feature. Al-Site Corp. v. VSI International Inc., 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999) ("Rarely, however, will the skill in the art component operate to supply missing knowledge or prior art to reach an obviousness judgment").

Thus, Applicant respectfully submits that the limitation of the claimed number of transducers to between about 32 and 64 ultrasound transducers (as well as the limitation of the

claimed range of azimuths for the applying ablating energy to between 180 and 359 degrees and sufficiently smaller than 360 degrees to avoid inducing a deficit in a phrenic nerve of the subject) is not an obvious design consideration for a person skilled in the art.

Based on the above, Applicant respectfully submits that the combined teaching of Crowley in view of the teaching of Moore and/or obvious design considerations, at best, teaches a catheter having (a) an array of annular transducers adapted to apply ablating energy to tissue and (b) an array of imaging transducers arranged circumferentially about the catheter, but does not teach or suggest an apparatus for use with a subject, comprising: (i) a catheter having a longitudinal axis and having distal portion, and (ii) an ultrasound array comprising between about 32 and 64 ultrasound transducers circumferentially arranged around the longitudinal axis at the distal portion, and adapted to operate in a phased array mode to apply ablating energy to tissue of the subject located in a range of azimuths, with respect to the longitudinal axis, that is less than 360 degrees, including a range of azimuths between 180 and 359 degrees, wherein when the catheter is threaded through the venous system and disposed in a vicinity of an ostium of a pulmonary vein of the subject, the range of azimuths is sufficiently smaller than 360 degrees to avoid inducing a deficit in a phrenic nerve of the subject, as set forth in claim 1.

In the May 11, 2009 Office Action, the Examiner rejected claims 5-11 under 35 U.S.C. §103(a) as allegedly unpatentable over Crowley in view of Moore and U.S. Patent No. 6,117,101 to Diederich et al. (hereinafter "Diederich").

On page 4 of the May 11, 2009 Office Action, the Examiner cited column 32, lines 52-63, column 39, lines 38, and Figure 18a of Diederich as allegedly disclosing a catheter ablation device that employs an ultrasound array for providing ablative energy at specific azimuth ranges.

Diederich, as presently understood by Applicant, describes a circumferential ablation device having a transducer that is separated into individually excitable transducer sectors.

Applicant notes that Diederich is particularly vague and lacks any particular guidance to one of ordinary skill in the art as to the number of ultrasound transducers to incorporate into an array and the control of such ultrasound transducers to apply ablating energy in a range of azimuths with respect to the longitudinal axis of the catheter. For example, Diederich only generally describes that the transducer can have an annular shape so as to emit ultrasonic energy around the entire circumference of the ablation device or alternatively be configured to have a single active sector with 180 degree exposure.

Based on the above, Applicant respectfully submits that Diederich fails to cure the above-described deficiencies of Crowley and Moore. Specifically, Diederich fails to teach or suggest that the claimed number of transducers is limited to "between about 32 and 64 transducers" and that the claimed range of azimuths for the applying ablating energy is limited to "between 180 and 359 degrees", and "sufficiently smaller than 360 degrees to avoid inducing a deficit in a phrenic nerve of the subject", as set forth in claim 1 and incorporated by reference into claims 5-11.

For the above-stated reasons, Applicant respectfully submits that claim 1 is patentable over the cited references. Moreover, Applicant respectfully submits that claims 5-11 are patentable over the cited references based at least upon their dependence to claim 1.

In view of the above, it is respectfully submitted that this application is in condition for allowance. Accordingly, it is respectfully requested that this application be allowed and a Notice of Allowance issued. If the Examiner believes that a telephone conference with Applicant's attorneys would be advantageous to the disposition of this case, the Examiner is requested to telephone the undersigned.

Respectfully submitted,

Paul J. Esatto Jr.
Registration No.: 30,749

Scully, Scott, Murphy & Presser, P.C.
400 Garden City Plaza, Suite 300
Garden City, New York 11530
(516) 742-4343
PJE/WC:vh